DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

September 29, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Eddie M. Madden
Owner/President
Madden's Pharmacy
62 Chestnut Street
Elberton, Georgia 30635

WARNING LETTER

Dear Mr. Madden:

An inspection of your medical oxygen transfilling facility was conducted on September 15, 1997, by Investigator Leah M. Andrews. Our investigator documented numerous significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include identity and purity, prior to release. Although the H and T cylinders available for transfilling were labeled as Oxygen USP, you could provide no other assurance as to the purity or suitability of these drug products. You could provide no analytical test results for any of the H and T cylinders you have utilized for transfilling. No Certificate of Analysis had been received for any incoming cylinder. In addition, you have conducted no purity or identity testing on any of the cylinders you have routinely transfilled at your facility over the last year. You did not have the capability to appropriately test transfilled cylinders. In fact, you did not even have an oxygen analyzer at your facility.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. Unfortunately, no one at your firm had received training commensurate with their responsibilities.

This lack of training was exemplified by your firm's total lack of compliance with the applicable regulations for the transfilling of Oxygen USP. No employee at your firm was familiar with the appropriate quality control steps required for transfilling. Prefill and filling tests, such as odor testing, leak testing, and venting of cylinders, were not being performed. You did not have the necessary equipment to purge the cylinders prior to filling.

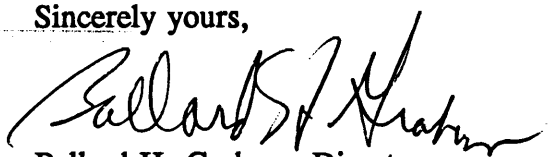
You have failed to establish formalized written procedures to cover any of the various aspects of the transfilling operation. None of the required production records were maintained to document each significant step in the transfilling of this drug product. No records were available of the number of cylinders filled, the parent lot of oxygen used, the dates cylinders were transfilled, or any lot numbers utilized by your firm.

At the conclusion of the inspection, Investigator Andrews issued her Inspectional Observations (FDA 483) to and discussed her findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. We are in receipt of your response dated September 23 which indicated your desire to cancel your registration. You had stated to Investigator Andrews that if you canceled your registration your plans would be to permanently discontinue transfilling. Your response to this letter should address any proposed actions regarding the oxygen cylinders currently in distribution which have not been properly tested. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District